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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,896	07/14/2003	Paul G. Ahlquist	960296.00096	7353

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
05/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	10/618,896	AHLQUIST ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 2-14-08 has been entered. Claims 26 and 27 have been amended. Claims 21-30 are pending. Claims 26 and 27 are under consideration.

It should be noted that claims 1-20 have been canceled in Applicants' preliminary amendment filed on 7-14-03. Therefore, only claims 21-30 are pending in the instant invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed on 2-14-08 necessitates this new ground of rejection.

The phrase "a substance as a positive strand RNA antiviral agent" in claims 26 and 27 is vague and renders the claims indefinite. It is unclear whether the substance is considered as a "positive strand RNA" or as an antiviral agent against "positive strand RNA virus".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 26 and 27 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and is repeated for the reasons set forth in the preceding Official action mailed 10-15-07. Applicant's arguments filed 2-14-08 have been fully considered but they are not persuasive.

Applicants argue that the claims have been amended to recite "a yeast or mammalian delta9 fatty acid desaturase enzyme" and there is much homology and functional equivalent among such genes, and it is known that the corresponding delta9 fatty acid desaturase from mammals can functionally replace the yeast protein (amendment, p. 8-9). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 10-15-07. The claims still encompass a genus of numerous different delta9 fatty acid desaturase enzymes derived from various organisms, such as humans, rats, mice, canine, feline, sheep, cows, horses, monkeys, whales, and other mammals etc., and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification fails to provide the structural features that contribute to the biological function of various delta9 fatty acid desaturase enzymes. The specification only discloses delta9 fatty acid desaturase enzyme encoded by OLE1 gene in yeast. The state of the art shows only the presence of OLE1 gene of Histoplasma capsulatum (a dimorphic pathogenic fungus) and OLE1 gene of yeast Saccharomyces cerevisiae at the time of the invention. Applicants apparently do NOT have possession of various mammalian delta9 fatty acid desaturase enzymes at the time of the

invention. Yeast delta9 fatty acid desaturase enzyme may have mammalian homologs, however, possession of yeast delta9 fatty acid desaturase enzyme does not make it the possession of various mammalian homologs. Further, biological function of a protein was unpredictable from mere amino acid sequence at the time of the invention. The biological function of various mammalian homologs of yeast delta9 fatty acid desaturase enzyme was unpredictable from the protein function of yeast delta9 fatty acid desaturase enzyme at the time of the invention. Thus, it is concluded that the written description requirement is not satisfied for the use of the genus of numerous different delta9 fatty acid desaturase enzymes derived from various organisms as claimed.

5. Claims 26 and 27 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and is repeated for the reasons set forth in the preceding Official action mailed 10-15-07. Applicant's arguments filed 2-14-08 have been fully considered but they are not persuasive.

Applicants cite Exhibits A-D and argue the universal dependence of RNA replication on expanded, rearranged membranes, on the synthesis and physical characteristics of these membranes in positive strand RNA viruses. Applicants argue that delta9 desaturase enzyme converts SFAs to UFAs and positive strand RNA replication is strongly dependent on UFA levels, and modulating composition of membrane helps to identify useful antiviral agents (amendment, p. 9). This is not found persuasive because of the reasons set forth in the preceding

Official action mailed on 10-15-07. Although delta9 desaturase enzyme converts SFAs to UFAs, positive strand RNA replication is strongly dependent on UFA levels and the synthesis and characterization of the membranes, however, there is no evidence of record that shows a correlation between a decrease in stability or inhibition of activity of various OLE1 proteins and an antiviral therapy. There is a possibility that a feedback regulation of UFAs can regulate the activity of delta9 desaturase enzyme, the UFAs levels may be regulated by mechanism other than delta9 desaturase enzyme, or some other enzyme can compensate the activity or instability of the delta9 desaturase enzyme such that a decrease in stability or inhibition of activity of delta9 desaturase enzyme does not result in any antiviral activity. There is no evidence of record that a substance effecting a decrease in stability or inhibition of activity of various OLE1 proteins would be indicative of said substance as an antiviral therapy agent. Even if there is a correlation between a decrease in stability or inhibition of activity of various OLE1 proteins and an antiviral therapy, different OLE1 proteins could have different biological functions and there is no evidence of record that shows those different OLE1 proteins would have same effect on the BMV RNA replication or various viral infections. Since OLE1 proteins other than the yeast OLE1 protein might not have any effect on BMV RNA replication or any viral infection. Therefore, a substance effecting a decrease in stability or inhibition of activity of those OLE1 proteins would not be indicative of said substance as an antiviral therapy agent.

Applicants argue that the claims have been amended to recite "a method of evaluating a substance as a positive strand RNA antiviral agent" and BMV are inhibited when the stability of the delta9 desaturase enzyme is affected (amendment, p. 9-10). This is not found persuasive because of the reasons set forth in the preceding Official action mailed on 10-15-07 and the

reasons set forth above. As discussed above, the phrase "a substance as a positive strand RNA antiviral agent" in claims 26 and 27 is vague. It is unclear whether the substance is considered as a "positive strand RNA" or as an antiviral agent against "positive strand RNA virus". Further, positive strand RNA viruses still encompass numerous different RNA viruses. Different OLE1 proteins from various positive strand RNA viruses could have different biological functions and there is no evidence of record that shows those different OLE1 proteins would have same effect on the BMV RNA replication or various positive strand RNA viral infections. A yeast OLE-1 mutant inhibiting BMV-directed gene expression does not necessarily mean that decrease in stability or inhibition of activity of yeast or mammalian delta9 desaturase enzyme would be correlated to antiviral activity against various positive strand RNA viruses. OLE1 proteins other than the yeast OLE1 protein might not have any effect on BMV RNA replication or any viral infection. Therefore, a substance effecting a decrease in stability or inhibition of activity of those OLE1 proteins would not be indicative of said substance as an antiviral therapy agent. Thus, the claims remain rejected under 35 U.S.C. 112 first paragraph.

Conclusion

No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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